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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,671	06/26/2001	Derek A. Pratt	N-6636	9766

7590 09/19/2002  
STITES & HARBISON  
424 CHURCH STREET  
SUITE 1800  
NASHVILLE, TN 37219

EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 09/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



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Michael L Goldman  
Nixon & Peabody  
Clinton Square  
PO Box 31051  
Rochester, NY 14603

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# Office Action Summary

Application No.

09/891,671

Applicant(s)

PRATT ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 11-13, 17-22, 24, 25, 27, 28, 30, and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10 is/are rejected.
- 7) ☒ Claim(s) 14-16, 23, 26, 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6, 10, 14-16, 23, 26, and 29, drawn to compounds of formulae 4, 7, and 9 as well as their methods of use, classified in class 544, subclass 298.
  - II. Claims 7-9, 17-19, 24, 27, and 30, drawn to compounds of formulae 5 and 8 as well as their methods of use, classified in class 546, subclass 290.
  - III. Claims 11, 13, 20-22, 25, 28, and 31, drawn to compounds of formula 6 and their methods of use, classified in class 546, subclasses 113, 115.
  - IV. Claim 12, drawn to compounds of formula 10 and its methods of use, classified in class 546, subclass 122.

The inventions of groups I - IV differ from each other because each group is drawn to a ring system that is distinct and patentable over each other. Essentially, these are four independent inventions as compounds of one group can be utilized alone, and not in combination of those in other groups. Note, with a variable core as such, the common property is not enough to keep four groups in the same Markush claim. Furthermore, a prior art that renders obvious one invention would not do so to the other. Thus, restriction for examination purpose as indicated is proper. However, should applicant traverse on the ground that the four groups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the four groups to be obvious variant or clearly admit on the record that this is the case.

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In either instance, if the examiner finds one of the invention unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

2. During a telephone conversation with Mr. Richard Myers on 9-2-02 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, 10, 14-16, 23, 26, and 29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-9, 11-13, 17-22, 24, 25, 27, 28, 30, and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 5, 6, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 3 lacks antecedent basis because it recites  $R_1$  as "alkyl" which is not defined for  $R_1$  in claim 1.
- b. Claim 5 and 6 lack antecedent basis because variables  $R_1$ - $R_3$  of formula 7 are not consistent with those of formula 4 in claim 1.
- c. Claim 10 lacks antecedent basis because it depends on claim 7, but recites a diamino-pyrimidinol formula. It appears that claim 10 should be dependent on claim 1.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

d. **LaMattina** (US 4,554,276 – cited on IDS): See Examples 7-9;

e. **Maurer et. al.** (US 5,010,193 – cited on IDS): See Table 5 (especially last two compounds on column 16, wherein R is  $-\text{N}(\text{CH}_3)_2$  or  $-\text{N}(\text{C}_2\text{H}_5)_2$ ), and Table 8 (Example C5).

The claimed formulae 4 and 7 embrace the disclosed compounds when their  $\text{R}_1$ - $\text{R}_3$  take on the following meanings:

- i. In formula 4, either both  $\text{R}_1$  and  $\text{R}_2$  are hydrogen, or  $\text{R}_1$  is hydrogen while  $\text{R}_2$  is an alkyl group.  $\text{R}_3$  is amino, N-alkylamino, or N,N-dialkylamino.
- ii. In formula 7,  $\text{R}_1$  and  $\text{R}_2$ , each independently represents hydrogen, methyl or ethyl.  $\text{R}_3$  is either hydrogen or methyl.

5. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by **Henrie, II et. al.** (US 5,521,192 – cited on IDS). Compound 7 in Table 1 is embraced by the claimed formula 4 with the following substituents:

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iii.  $R_1$  and  $R_3$  represent amino

iv.  $R_2$  represents an alkyl group.

6. Claims 1, 2, 4, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Hill et. al.** (US 4,374,136 – cited on IDS). The starting material in Example 1 on column 6 (i.e., 2,4-*Diamino-5-hydroxy-6-methylpyrimidine dihydrogen sulphate*) is embraced by the salts and/or inherently embraced by compounds of formulae 4 and 9 with the following substituents:

v. In formula 4,  $R_1$  and  $R_3$  represent amino while  $R_2$  represents an alkyl group.

vi. In formula 9,  $R_1$ ,  $R_2$ ,  $R_4$ , and  $R_5$  are hydrogen while  $R_3$  is methyl.

7. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by **Walker et. al.** (US 4,711,888 – cited on IDS). The title compound of Example 5 is embraced by the compound recited in claim 3 with  $R_1$  and  $R_2$  as alkyl groups while  $R_3$  is an N,N-dialkylamino group.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by **Jovanovic** (Can. J. Chem., Vol. 62(6), 6/1984, pp. 1176-1180). Compound #4 on page 1176 is embraced by the claimed formula 4 with  $R_1$  and  $R_2$  as hydrogen while  $R_3$  represents an electron donating group.

### ***Claim Objections***


9. Claims 14-16, 23, 26, 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. References of record do not relate pyrimidinol compounds to the inhibition of oxidation or antioxidation in therapeutical uses.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**



T. Truong

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September 10, 2002